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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/432,881 | 11/02/1999 | MICHELINE MARKEY | 15662-000900 | 1727 |

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

NGUYEN, HELEN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1617

DATE MAILED: 05/23/2002

14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/432,881

Applicant(s)

MARKEY ET AL.

Examiner

Helen Nguyen

Art Unit

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-- The MAILING DATE of this communicati n appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-99 is/are pending in the application.
- 4a) Of the above claim(s) 3-5, 7-13, 19-47 and 52-99 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 6, 14-18 and 48-51 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

The amendment of paper no. 13, filed April 1, 2002, is acknowledged.

All arguments are fully considered.

Claim 2 is amended.

Claims 3-5, 7-13, 19-47 and 52-99 are non-elected.

Claims 1, 2, 6, 14-18, and 48-51 are pending and presented for examination.

Claim rejection- 35 USC § 112

The rejection of claim 2 of record under 35 U.S.C. 112, second paragraph is made moot due to the amendment of paper no. 13 to correct the typographical error.

Claim rejection- 35 USC § 103

Applicants' arguments regarding the rejection under 35 U.S.C. 103 set forth in the previous office action of paper no. 13, filed April 1, 2002, have been considered but they are not persuasive. Therefore, the rejection under 35 U.S.C 103 is maintained for reasons as follows:

❖ The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this

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title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 6, 14-18 and 48-51 are rejected **under 35 U.S.C. 103(a)** as being unpatentable over Shell (WO 97/47285, see IDS paper no. 8 filed on July 2, 2001) in view of Acharya (US Patent No. 5,686,094) and Sewester et al. (Facts and Comparisons).

Shell (WO 97/47285) teaches a controlled release composition comprising an active drug and a solid matrix which swells or expands upon contact with gastric fluid in the fed mode (see abstract). Hydroxypropyl cellulose is specified in the solid matrix (see page 4, line 32).

Shell does not teach an active drug docusate.

Acharya teaches docusate as a laxative (see column 7, lines 39, 57-58 and column 8, line 6). Controlled release is disclosed (see column 5, line 44). Hydroxypropyl cellulose is specified (see column 5, lines 53-54).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add docusate to the composition of Shell to achieve the beneficial effect of an additional laxative treatment in view of Acharya.

As to the claimed amount of docusate, it is well known in the art that the therapeutic range of docusate is within the claimed invention (see Facts and Comparisons, page 322a).

Applicants argue that the second reference (Acharya) does not teach docusate to induce the fed mode. However, the motivation to combine needs not be Applicants' inventive concept. See In re Dillon, 16 USPQ2d 1897.

- Applicants argue docusate as a fed mode inducer. However, an intended use is not considered a patentable limitation during prosecution of a composition claim before the USPTO.
- Applicants argue that there is no purpose in putting a laxative in a device that remains in the stomach. However, Applicants assertion is mere opinion. Applicants cite no teaching in either reference that teaches away from docusate in a device retained in the stomach.

Conclusion

Claims 1, 2, 6, 14-18 and 48-51 are rejected.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes

that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Helen Nguyen whose telephone number is (703) 605-1198. The examiner can normally be reached on M-F (9:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's primary, Edward J. Webman can be reached at (703) 308-4432 or her supervisor, Minna Moezie can be reached at (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Helen Nguyen
Patent Examiner

May 22, 2002



EDWARD J. WEBMAN
PRIMARY EXAMINER
GROUP 1500